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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,759	09/19/2005	Ignacio Blanco Blanco	034284-003	6945

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/549,759	BLANCO, IGNACIO BLANCO	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on August 2, 2006 has been received and entered. Claims 6, 8, 10, 13 and 14 have been amended. Claims 1-5 have been canceled. No claims have been added. Accordingly, claims 6-16 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file- a certified copy of Applicant's Spanish Application No. 200402282, filed on September 24, 2004. Should Applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d), however, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action (see MPEP 201.14(a)). This a requirement for all non-provisional applications in the event of any cited intervening art that Applicant wishes to overcome (see below).

Claim Rejections - 35 USC § 112, first paragraph

In view of Applicant's amendments to the claims, these rejections are withdrawn.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicant's amendments to the claims, the rejections in the previous Office action are withdrawn.

Claims 6-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, the preambles recite simply a method of treatment, while the claimed invention is drawn to a method of treating fibromyalgia. The dependent claims recite simply "Method," rather than, e.g., "The method of claim 6." Additionally, the claims recite the abbreviation AAT, rather than alpha-1 antitrypsin, rendering the meaning of the claims unclear. If a compound or molecule is recited in the claims, its full name must appear. Appropriate correction is required. For example, the claims may be amended as indicated below.

Claim 7 is unclear and confusing because it recites a particular dose range that is administered "or multiples of these quantities adjusted according to the time interval foreseen until the next dose, in a proportional manner." This phrase is confusing, and the intended meaning cannot be determined, as the specification provides no further explanation. The foreseen time interval is indefinite and cannot be determined. Additionally, a claim may recite one dose or dose range only, i.e., 25-60 mg/kg body weight per week. Further, the claim recites 25-6, rather than 25-60 as in the specification. Clarification is requested as to whether Applicant meant 6-25 or 25-60. Appropriate correction is required. For example, the claims may be amended as indicated below, amended claims 6 and 7 serving as an example for the others.

6. (currently amended) A method of ~~treatment~~ treating fibromyalgia comprising, administering to a patient diagnosed with fibromyalgia about 15 to about 360 mg alpha-1 antitrypsin (AAT) ~~AAT~~ per kg patient body mass, and repeating the administration at least once with a periodicity of between 3 and 31 days.

7. (currently amended) The method ~~Method,~~ according to claim 6, wherein alpha-1 antitrypsin (AAT) ~~AAT~~ is administered at a dose of between 25 and 60 mg/kg per week ~~every week or~~

~~multiples of these quantities adjusted according to the time interval foreseen until the next dose, in a proportional manner~~.

Claim Rejections - 35 USC § 101

In view of Applicant's amendments to the claims, this rejection is withdrawn.

Claim Rejections - 35 USC § 102

Claims 6-16 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. The following reference, Blanco et al., "Alpha1-antitrypsin replacement therapy controls fibromyalgia symptoms in 2 patients with PI ZZ alpha1-antitrypsin deficiency," J Rheumatology 31(10):2082-2085, October 2004, by a different inventive entity than the instant application discloses the treatment of fibromyalgia by administering alpha1-antitrypsin (AAT). Exact doses and dosing schedules are not provided, but the article discloses that this treatment of two sisters began in 1992. The two sisters regularly saw a number of doctors and were part of a family study of subjects with AAT deficiency that began in 1984. Thus, the treatment of fibromyalgia with AAT has been public knowledge since 1992, information known at least to the family, their doctors, the people with whom the doctors communicated, and those involved with the Spanish AAT Deficiency Registry and the Alpha1 International Registry (AIR) (see pp. 2082 and 2084, Case Reports). AIR is a multinational research organization of 20 countries, including the U.S. Detailed clinical information on AAT deficiency research is sent to a database in Malmö, Sweden, where it is made accessible to researchers in other countries (see Alpha One International Registry (AIR) homepage, http://www.aatregistry.org/, printed on August 18, 2006). Because the patients in these case studies have been members of AIR since the late 1990's, the treatment methods in the case studies were known to doctors in the U.S. more than one year before the filing date of the instant invention.

The AAT was administered intravenously on a weekly basis, as recited in the claims, and the amount administered increased the serum level of AAT to an amount about 8-fold higher than the basal level after 24 hours (see claim 13) and to an amount about 100% over basal level after 7 days (see claims 8-9). Although the dose in mg AAT/kg body weight is not indicated, the amount given appears to be the same as in the instant application as the same result is achieved. It is not clear, though, if Blanco et al. are reporting their own work or that of others, in connection with the work of Blanco et al.'s genetic studies on AAT deficiency.

An issue of public use or on sale activity has been raised in this application (see MPEP 2133.02 and 2133.03(II)(b)). In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows. Applicant is requested to provide information specifying the doses and dosing schedules of AAT administered to the two sisters and the results obtained. Applicant is also requested to indicate who knew about these case studies, that is, the extent to which these case studies were discussed and published, when and where. If Applicant is aware of any other relevant prior art, in particular, earlier publications of this work, Applicant is required to submit this information in an IDS (see MPEP 2001 and 37 CFR 1.56).

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

Therefore, a holding of anticipation is required.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-16 are rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blanco et al., "Alpha1-antitrypsin replacement therapy controls fibromyalgia symptoms in 2 patients with PI ZZ alpha1-antitrypsin deficiency," J Rheumatology 31(10):2082-2085, October 2004. The teachings of Blanco et al. are discussed above. This publication is prior art because Applicant has not perfected his priority claim, as discussed above, because a certified English translation of the priority document has not been received. Blanco et al. disclose the instant invention as recited in claims 8, 9 and 13. As also discussed above, the dose of AAT administered cannot be determined from the reference, but because Blanco et al. disclose the same results as Applicant, the same dose appears to have been administered.

The dose of a therapeutic agent to be administered, however, is a result-effective parameter which, art at the time of Applicant's invention was routinely optimized by one of ordinary skill in the art of medicine or pharmacology. Thus, if a different dose was used in the case studies reported by Blanco et al., any claimed variations in Applicant's method with respect to this parameter clearly would have been obvious at the time of Applicant's invention, the optimization of dosing being well within the capabilities of the artisan of ordinary skill at the time of Applicant's invention.

In view of the foregoing, a holding of anticipation is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-08-18

Rosanne Kosson

JON WEBER
SUPERVISORY PATENT EXAMINER